REMARKS

Claims 1-4, 8-11, 68, 80-83 and 86-90 were pending prior to this amendment. Claims 1, 4, 10, 11 and 89 are amended herewith. Support for the claim amendments can be found, for example, on page 3, lines 13-17, and page 16, lines 27 and 28, of the specification. Claims 1-4, 8-11, 68, 80-83 and 86-90 are, therefore, currently pending with claims 1 and 4 being independent claims.

Applicant expressly reserves the right to pursue the subject matter canceled by this amendment. No new matter has been added.

Rejections Under 35 U.S.C. §101

The Examiner has rejected claims 1-4, 8-11, 68, 80-83 and 86-90 under 35 U.S.C. §101 for lacking patentable utility. The Examiner alleges that the application has asserted no utility specific to the claimed invention. The Examiner has further alleged that there is no identification of a function for the protein encoded by SEQ ID NO: 1, nor any correlation of the presence of the polynucleotide (i.e., gene expression of SEQ ID NO: 1) or the protein with any specific cardiac pathology. Therefore, it is the Examiner's conclusion that the claims lack a substantial and specific utility.

Applicant respectfully traverses the rejection. The Applicant need only make one assertion of utility for the claimed invention to satisfy the utility requirement. *Brooktree Corp v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 USPQ2d 1401, 1412 (Fed. Cir. 1992.) Applicant has, in fact, provided a number of substantial and specific uses for the invention as claimed. As argued previously, the teachings provide that the complete MIVR-1 nucleic acid, polypeptide or fragments thereof have utility in both diagnostic and therapeutic applications (See, e.g., page 2, lines 11-31.) For instance, MIVR-1 nucleic acids and polypeptides can be used in the treatment of cardiovascular disorders (e.g., myocardial infarction, stroke, arteriosclerosis, heart failure and cardiac hypertrophy) (See, e.g., page 2, lines 2-13.) MIVR-1 molecules can also be used in the diagnosis of such cardiovascular disorders.

In order to violate the utility requirement, the claimed invention must be shown to be "totally incapable of achieving a useful result." *Brooktree Corp v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 USPQ2d 1401, 1412 (Fed. Cir. 1992.) Applicant maintains that the Examiner has not demonstrated this. Contrary to the assertion that there is no identification

of a function for the protein encoded by SEQ ID NO: 1, the specification clearly indicates that MIVR-1, the protein encoded by SEQ ID NO: 1, has anti-apoptotic activity (See, e.g., page 2, lines 25 and 26.) In addition, contrary to the assertion that there is no correlation of the presence of the MIVR-1 polynucleotide or protein to any specific cardiac pathology, the specification provides that MIVR-1 is heavily expressed in human aorta smooth muscle cells following strain. Strain (i.e., biomechanical strain or stress) is recognized by those of ordinary skill in the art to be a hypertrophic agonist (See, e.g., Keulenaer, et al. *Circ. Res,* 2002; 90: 690-696.) Therefore, the teachings provided clearly demonstrate the correlation of MIVR-1 upregulation with at least increases in cardiac strain and, correspondingly, with an elevated risk of cardiac hypertrophy.

Furthermore, the teachings of the specification provide an additional observation, namely, that while MIVR-1 expression is upregulated in cells undergoing cardiac strain, apoptosis is decreased in such cells. It is known by those of ordinary skill in the art that apoptosis is indicative of cardiac conditions, such as myocardial infarction, stroke, arteriosclerosis and heart failure (See, e.g., Gutstein and Marks, *Heart Vessels.* 1997; Suppl. 12: abstract.) Therefore, as MIVR-1 is correlated (inversely) with apoptosis, MIVR-1 is likewise an indicator of such cardiac conditions.

Based on the foregoing, Applicant maintains that the specification provides at least the above-mentioned credible assertions of utility for using the claimed invention. Therefore, withdrawal of this rejection is respectfully requested.

The Examiner has also rejected claims 10 and 11 under 35 U.S.C. §101 as being directed to non-statutory subject matter. The Examiner maintains that the claims read on host cells within a human being.

Without conceding the correctness of the Examiner's position, and in the interest of expediting the prosecution of this application, Applicant has amended claims 10 and 11. Therefore, the rejection is now moot.

Accordingly, withdrawal of this rejection is respectfully requested.

Rejections Under 35 U.S.C. §112

The Examiner has rejected claims 1-4, 8-11, 68, 80-83 and 86-90 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such

a way as to enable one of ordinary skill in the art to use the invention. The Examiner alleges that the application does not teach what disorders may be diagnosed using the claimed nucleic acids or encoded peptides.

Applicant respectfully traverses the rejection. As provided above, it is recognized by those of ordinary skill in the art that biomechanical strain or stress initiates cardiac hypertrophy. Therefore, the teachings provided, in the instant application, clearly demonstrate the correlation of MIVR-1 upregulation with the presence or risk of cardiac hypertrophy, and the claimed invention can be used at least for diagnostic purposes to determine the presence or risk of at least this condition in a subject. Furthermore, the specification also indicates that MIVR-1 upregulation correlates with a decrease in apoptosis, which, as described above, is known to be indicative of cardiac pathology. The claimed invention, therefore, can also be used to assess apoptotic levels and, it follows, cardiac conditions, such as myocardial infarction, stroke, arteriosclerosis, and heart failure.

With these teachings, in addition to the guidance provided in the instant specification, one of ordinary skill in the art is indeed enabled to use the claimed invention. One of ordinary skill in the art is enabled to use complete MIVR-1 nucleic acids, polypeptides or fragments thereof for at least the diagnosis of the conditions described immediately above. In addition, Applicant maintains that one of ordinary skill in the art is also enabled to use the claimed invention for therapeutic purposes, such as those, for example, described on pages 2-9. Contrary to the Examiner's assertion, the specification provides sufficient guidance for one of ordinary skill in the art to know how the claimed molecules can be used and for what pathologies they can be used for.

Furthermore, no evidence has been provided by the Examiner to sufficiently establish that the Applicant's assertions are not credible. The Examiner has provided no evidence that sufficiently demonstrates that Applicant's teachings should be doubted or that one of ordinary skill in the art would not be able to use the claimed nucleic acids for the purposes described herein and in the instant specification.

Accordingly, withdrawal of this rejection is respectfully requested.

The Examiner has also rejected claims 10 and 11 under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. The Examiner asserts that the

specification is not enabling for host cells comprised within either the human patient or the transgenic animal.

Applicant does not agree with the Examiner's rejection of the claims; however, as the claims have been amended as described above, the rejection is now moot.

Accordingly, withdrawal of this rejection is respectfully requested.

Rejections Under 35 U.S.C. §102

The Examiner has rejected claims 1, 4, 68, 81, 88 and 89 under 35 U.S.C. §102(b) as being anticipated by Xu et al., *Genomics* 66: 257-63. The Examiner alleges that Xu et al. teach two DNA probes, one of which is complementary to a portion of the nucleic acid of SEQ ID NO: 3, while the other corresponds to a portion of the nucleic acid of SEQ ID NO: 3.

Without conceding the correctness of the Examiner's assertions, Applicant has amended claims 1 and 4. The rejection, therefore, is now moot.

Accordingly, withdrawal of this rejection is respectfully requested.

CONCLUSION

In view of the foregoing amendments and remarks, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes, after this amendment, that the application is not in condition for allowance, the Examiner is requested to call the Applicant's representative at the telephone number listed below.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,
Lee et al., Applicant

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